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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,422	04/04/2006	Pyare L. Seth	Q88273	4203
23373	7590	10/20/2006	EXAMINER	
SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			ROBERTS, LEZAH	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 10/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/540,422	Applicant(s) SETH, PYARE L.	
	Examiner Lezah W. Roberts	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☒ Claim(s) 5-11 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>24 June 2005</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Information Disclosure Statement

The listing of references in the Search Report is not considered to be an information disclosure statement (IDS) complying with 37 CFR 1.98. 37 CFR 1.98(a)(2) requires a legible copy of: (1) each foreign patent; (2) each publication or that portion which caused it to be listed; (3) for each cited pending U.S. application, the application specification including claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion, unless the cited pending U.S. application is stored in the Image File Wrapper (IFW) system; and (4) all other information, or that portion which caused it to be listed. In addition, each IDS must include a list of all patents, publications, applications, or other information submitted for consideration by the Office (see 37 CFR 1.98(a)(1) and (b)), and MPEP § 609.04(a), subsection I. states, "the list ... must be submitted on a separate paper." Therefore, the references cited in the Search Report have not been considered. Applicant is advised that the date of submission of any item of information or any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the IDS, including all "statement" requirements of 37 CFR 1.97(e). See MPEP § 609.05(a).

Claims

Claim Objections

Claims 5-11 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Claim Rejections - 35 USC § 112 – Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

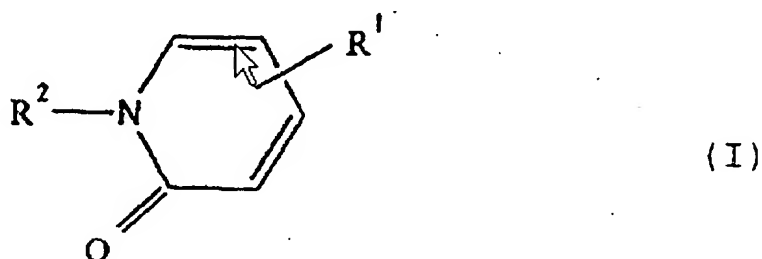
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 3-4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification states that the invention comprises, a liquid pharmaceutical composition comprising a pyridone derivative for the treatment of dermatological disorders, particularly fibrotic dermatoses such as fibrotic lesional tissues, contiguous warts and the like or contact dermatitis, keloids, scars after burn surgery and the like. The liquid compositions have a high concentration of the pyridone derivative without

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recrystallization. Nowhere, however, does it specify which particular compounds have the desired characteristic of treating the dermatological disorders and having stability while as a liquid, other than those having the structural formulae



wherein R¹ is an

alkyl group optionally having a substituent and R² is a phenyl group optionally having a substituent. The examples of the alkyl group optionally having a substituent as R¹ include a C₁₋₆ lower alkyl group such as methyl, ethyl, propyl, isopropyl, butyl, isobutyl, pentyl or hexyl and an alkyl group having a substituent in which said lower alkyl group is substituted with a halogen atom such as fluorine or chlorine; a carboxyl group; an alkoxycarbonyl group such as methoxycarbonyl or ethoxycarbonyl; or a substituent such as amino group. The alkyl group optionally having a substituent as R¹

may be substituted at any of the 3-position, 4-position or 5-position. The examples of the phenyl group optionally having a substituent as R^2 include a phenyl group and a phenyl group having a substituent in which the phenyl group is substituted with a C_{1-6} lower alkyl group such as methyl, ethyl, propyl, isopropyl, butyl, isobutyl, pentyl or hexyl; a halogen atom such as fluorine or chlorine; a carboxyl group; an alkoxycarbonyl group such as methoxycarbonyl or ethoxycarbonyl; or a substituent such as amino group.

What the inventors did not do is succeed in taking the last, critical step of actually isolating compounds having substituents other than those disclosed above, or at least of developing a process through which one skilled in the art would be directly led to such other compounds. See Univ. of Rochester v. G.D. Searle, 68 USPQ2d 1424, 1430-33 (DC WNY 2003).

The appearance of mere indistinct words in a specification or a claim (here an R_1 group being an alkyl group optionally having a substituent and R_2 a phenyl group optionally having a substituent), even an original claim, does not necessarily satisfy the written description requirement. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. Univ. of

Rochester v. G.D. Searle, 69 USPQ2d 1886, 1892 (CAFC 2004). A description of what a material does, rather than of what it is, usually does not suffice to provide an adequate written description of the invention. Univ. of Cal. v. Eli Lilly, 119 F.3d 1559, 1568 (Fed. Cir. 1997). Furthermore, to the extent that a functional description can meet the requirement for an adequate written description, it can do so only in accordance with PTO guidelines stating that the requirement can be met by disclosing "sufficiently detailed, relevant identifying characteristics," including "functional characteristics when coupled with a known or disclosed correlation between function and structure." Univ. of Rochester v. G.D. Searle, 68 USPQ2d 1424, 1432 (DC WNY 2003). No such correlation has been disclosed here.

The examiner recognizes that the fact situation in the Rochester cases was extreme, with Applicant there disclosing no (or possibly one) specific compounds. The reasoning provided by the court can be fairly extended to less extreme situations (*i.e.*, where a limited number of species is actually disclosed, such as here), however, given the court's recognition (Rochester (2003) at 1431) that:

[I]n claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus.

As was the case in Rochester, there is no such specificity here, nor could one skilled in the art identify any particular compound, other than compounds having the structural formulae above.

Claim Rejections - 35 USC § 112 - Indefiniteness

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1) Claims 1-4 recite the phrase "a high concentration". When the specification is looked to for determining what is meant by the phrase, the specification recites "high concentration of more or less 25% by weight". This phrase is indefinite because it cannot be determined what is meant by more or less 25% and what range this encompasses. It appears to encompass concentrations less than 25% and more than 25%, which makes it indefinite.

2) Claims 1-4 recited the term "active". The term "active" is synonymous with the phrase "effective amount". The claims do not recite what the active ingredient is effective for. Therefore the claims are indefinite. See MPEP § 2173.05(c).

Claim Rejections - 35 USC § 102 – Anticipation

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1) Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Gadekar (US 3,839,346).

Gadekar teaches pharmaceutical compositions comprising N-substituted pyridones such as 5-methyl-1-phenyl-2-(1H) pyridone (see Abstract). The pyridones are formulated together with a pharmaceutically acceptable carrier including a liquid carrier or a solvent (col. 2, lines 65-67). In regards to the high concentration, it cannot be determined what is meant by "high concentration", see indefinite rejection supra. The reference anticipates the claims insofar as it teaches liquid compositions comprising pyridone derivatives and a solvent.

2) Claims 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by Scheiwe et al. (US 2006/0039931).

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Scheiwe et al. teach pharmaceutical compositions in the form of a cream preparation comprising an oil-in-water emulsion. The compositions comprise pyridone derivatives such as 5-methyl-1-phenyl-2-(1H) pyridone (paragraph 0024-0039). The compositions also comprise a surface-active solubilizer including diethylene glycol monoethyl ether (paragraph 0041). The reference anticipates the claims insofar as it teaches liquid compositions comprising pyridone derivatives and diethylene glycol monoethyl ether.

Claim Rejections - 35 USC § 103 - Obviousness

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gadekar (US 3,839,346) in view of Iyer et al. (US 2004/0033257).

The primary reference is discussed above in the anticipation section subsection

1. The reference differs from the instant claims insofar as it does not teach the compositions comprise diethylene glycol monoethyl ether as the solvent.

Iyer et al. discloses oral compositions comprising solvents useful for poorly soluble pharmaceuticals. The solvents include diethylene glycol monethyl ether, which acts as a powerful solubilizer for several poorly soluble drugs. It is soluble in water and ethanol (paragraph 0024). It also can act as a co-surfactant. The reference differs from the instant claims insofar as it does not disclose pyridone derivatives as the drugs that are solubilized.

It would have been obvious to one of ordinary skill in the art to have used a solvent such as diethylene glycol monethyl ether in the compositions of the primary reference motivated by the desire use a powerful solubilizer to dissolve a poorly soluble drug, as taught by the secondary reference.

Claims 1-4 are rejected.

Claims 5-11 are objected.

No claims allowed.

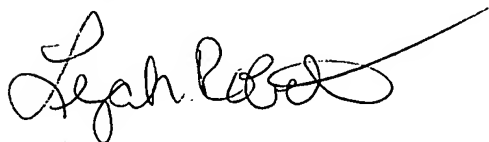
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

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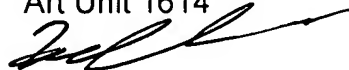
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lezah Roberts
Patent Examiner
Art Unit 1614

A handwritten signature in black ink, appearing to read 'Lezah Roberts', with a long horizontal flourish extending to the right.

Frederick Krass
Primary Examiner
Art Unit 1614

A handwritten signature in black ink, appearing to read 'Frederick Krass', with a long horizontal flourish extending to the right.